

Food and Drug Administration Rockville MD 20857

FILE COPY

June 04, 2002

Mr. Dale R. Agthe Legal Research Attorney University of Colorado Hospital Office of the General Counsel P.O. Box 6508, Mailstop F-415 Aurora, CO 80045-0508

Dear Mr. Agthe:

Your petition requesting the Food and Drug Administration to interpret the language of 503(d)(3)(A)(i) and (ii) was received by this office on 05/29/02. It was assigned docket number 02P-0246/CP 1 and it was filed on 06/04/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D.//Jaffe

Dockets Management Branch

02P-0246

ACK1